

**REMARKS/ARGUMENTS**

In response to the Final Office Action mailed January 15, 2009, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, Claim 6 is proposed to be amended, no new claims have been added and claims 9 and 10 were previously cancelled without prejudice so that Claims 6-8 remain pending. No new matter has been introduced.

Claims 6-8 were rejected under 35 U.S.C. §112, first paragraph. Applicants respectfully traverse. Amended claim 6 now states that the concentration of trichostatin A is in the range from about 5 nano molar to about 40 nano molar. These ranges are clearly shown in Figure 51. The x axis represents the molar concentration of trichostatin A in logarithmic form and clearly have that range in the sloped section. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 6-7 and 9-10 were rejected as being unpatentable over U.S. Patent Publication No. 2005/0065596 to Tseng et al. (Tseng) in view of Windecker et al. (Current Pharmaceutical Design) and U.S. Patent Application Protection No. 2005/0106203 to Roorda et al. (Roorda). Claims 6 and 8 were rejected as being unpatentable over Tseng in view of Windecker and Roorda and further in view of U.S. Patent Publication No. US 2002/0013616 to Carter et al. (Carter). These rejections are respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In *re* *Vaeck*, 947 F.2d, 488, 20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.”

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA

1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

None of the references, whether taken alone or in combination disclose or suggest the subject matter claimed in independent Claim 6. Specifically, none of the references disclose a combination of rapamycin and trichostatin A, where the concentration of trichostatin A is in the range from about 5 to about 40 nano molar. Tseng does disclose trichostatin A at 100 nano molar, 500 nano molar and 50 nano molar. However, the present invention is able to claim a lower range of about 5 to 40 because of its use in combination with rapamycin. Essentially, the present invention can use lower doses that are less dangerous and less efficacious due to its use in combination with rapamycin. None of the other references suggest this synergistic effect. In addition, there is no motivation to combine. Accordingly, all claims which depend therefrom are allowable over the cited art for the reasons given above. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

/Carl J. Evens/

By: \_\_\_\_\_

Carl J. Evens  
Reg. No. 33,874

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-2518  
Dated: March 11, 2009